

REMARKS

The Final Office Action dated July 14, 2008, has been fully considered. The present Amendment is intended to be a complete response thereto and to place the case in condition for allowance.

Claims 1-3 and 10-17 are pending. Claims 4-9 have been cancelled. Claim 1 has been amended to recite the transitional phrase “consisting of.”

THE CLAIMS ARE NOT ANTICIPATED OF OBVIOUS

Claims 1-3, 10-13, and 17 stand rejected under 35 U.S.C. § 102 as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over Borody (U.S. Patent No. 5,443,826). Claims 14, 15, 16 stand rejected under 35 U.S.C. § 103(a) as being obvious over Borody in view of Farmer et al. (U.S. Patent No. 7,374,753) and Armel (Cold Pasturization of certain bacteria by radionuclide gamma radiation. Applied Sugar Laboratories. January 1964) Applicant respectfully traverses the rejection.

Borody does not disclose every element of the claimed invention. The current claims “consist of” two steps 1) administering an antimicrobial composition; and 2) subsequently administering a probiotic agent. “The transitional phrase ‘consisting of’ excludes any element, step, or ingredient not specified in the claim.” MPEP 2111.03.

Borody discloses treatment of gastrointestinal disorders by (a) substantially complete removal of existing enteric flora; and (b) introduction of an array of predetermined flora into the gastrointestinal flora to completely change the enteric flora of the patient. Borody, column 3, lines 61-68. With regard to step (a), Borody discloses that

In the practice of the invention the patients [*sic*] existing enteric flora is removed by gastrointestinal lavage effected by ingestion of about 3 liters of a balanced salt solution with polyethylene glycol. Lavage is continued until the removal of the existing flora is as near complete as possible.

Column 5, lines 34-39. However, in column 5, lines 55-60, that “a preparatory course of appropriate antibiotics may be used,” such as, “Septrin for chronic yersiniasis, Metronidazole for ulcerative colitis, anti-TB therapy in Crohn's disease, or Vancomycin in chronic *Clostridium difficile* infestations.” The preparatory course is used before the removal of the enteric flora. *See, e.g.*, Example 1 (the patient was treated with metronidazole for one week before “oral ingestion of three liters balance salt solution with polyethylene glycol”). Thus, even with the antibiotic treatment, the method of Borody requires three steps (i) antibioltic administration; (ii) removal of existing enteric flora; and (iii) introduction of a predetermined flora.

On the contrary, the present invention does not remove the existing enteric flora. Borody completely removes the existing flora mechanically using a lavage solution, while the present invention removes only the abnormal microorganism using an antimicrobial agent. The present invention specifically targets a particular microorganism, while Borody removes the whole flora altogether. Clearly, the present invention is less traumatic as only a selected microorganism is removed rather than the whole flora. Therefore, Borody does not anticipate the present invention.

With regard to obviousness, there is no rationale for one of ordinary skill in the art to eliminate the step of removing the existing enteric flora in the method of Borody, nor has the Examiner offered one. This step is essential to his invention. Removal of this step would eviscerate Borody's teaching. Clearly, Borody teaches that the administration of antibiotic alone is insufficient. The whole existing enteric flora must be removed. (Example 1 discloses

mechanical removal of the enteric flora after treating the patient for one week with metronidazole for one week before). The administration of the antibiotic “may be used” (column 5, lines 56-57) while the removal of the existing enteric flora is a required step (column 3, lines 61-63) in the method of Borody. Therefore, one of ordinary skill would have no rationale to eliminate the step of removing the enteric flora from the method of Borody.

With regard to Farmer et al. and Armel, these references do not cure the deficiencies of Borody discuss above. Therefore, their combination with Borody still does not render the present invention obvious.

For the reasons noted, the present invention is not anticipated within the meaning of 35 U.S.C. § 102 or is obvious within the meaning of 35 U.S.C. § 103. Accordingly, Applicant respectfully request withdrawal of the rejections.

CONCLUSION

Applicant has responded to the Final Office Action mailed July 14, 2008. All pending claims are now believed to be allowable and favorable action is respectfully requested.

In the event that there are any questions relating to this Amendment or to the application in general, it would be appreciated if the examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (111828.0113). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, applicant hereby petitions under 37 C.F.R. 1.136(a) for an extension of time.

U.S. Application Serial No.: 10/729,949
Attorney Docket No.: 111828.0113
Reply to Office Action dated July 14, 2008

Any fees due are authorized above.

Respectfully submitted,

Date: October 23, 2008

/Charles R. Wolfe, Jr./
Charles R. Wolfe, Jr.
Registration No. 28,680

BLANK ROME LLP
Watergate
600 New Hampshire Avenue NW
Washington, DC 20037
Telephone: (202) 772-5800
Facsimile: (202) 772-5858